

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the application of

Inventor: Machold et al.

Divisional of Serial No. 09/707,257  
filed November 6, 2000

For: METHOD AND SYSTEM FOR  
CONTROL OF A PATIENT'S BODY  
TEMPERATURE BY WAY OF A  
TRANSLUMINALLY INSERTABLE HEAT  
EXCHANGE CATHETER

Prior Examiner: Robert L. Nasser

Group Art Unit: 3736

Client ID/Matter No. RADME-65146

**Express Mail Label No. EV 327058784 US**

August 20, 2003

**INFORMATION DISCLOSURE STATEMENT**

MAIL STOP PATENT APPLICATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

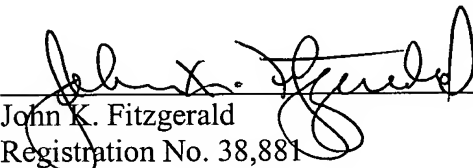
The documents listed on the enclosed form PTO-1449 (Modified) have come to the attention of the applicant and are submitted to the Office under 37 C.F.R. § 1.97. As provided under 37 C.F.R. § 1.98(a), copies of the listed references have not been enclosed because the information listed on Form PTO-1449 (Modified) was previously cited by or submitted to the Office in related application U.S. Serial No. 09/707,257, filed November 6, 2000, which is relied upon for an earlier filing date under 35 U.S.C. § 120. However, should the examiner wish to receive copies of these references, applicant will

them upon request. Applicant respectfully requests that the foregoing citations be considered and made of record. This statement is not a representation that all of the information cited is necessarily effective as prior art against the present application or that a prior art search was performed.

This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(b)(3), and therefore no fee is due. However, if a fee is in fact due, the Commissioner is authorized to charge any additional fee(s) to our Deposit Account No. 06-2425. A duplicate of this paper is enclosed.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:   
John K. Fitzgerald  
Registration No. 38,881

JKF/RCS:vmm/gbr

Enclosures: Form 1449 (Modified) (8 pgs.)  
Howard Hughes Center  
6060 Center Drive, Tenth Floor  
Los Angeles, CA 90045  
Telephone: (310) 824-5555  
Facsimile: (310) 824-9696  
Customer No. 24201  
22468.1

<b>FORM PTO-1449</b> (Modified)	Docket No.: RADME-65146	Serial No.:
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Applicant: Machold et al.	
Page 1 of 8	Filing Date:	Prior Art Unit: 3736

### UNITED STATES PATENT DOCUMENTS

*Exr's. Inits.	Cite #	Patent No.	Date	Name	Class	Sub Class	Filing Date (if applicable)
		2,308,484	01/19/43	Auzin et al.			
		3,425,419	02/04/69	Dato			
		3,726,283	04/10/73	Dye et al.			
		3,788,328	01/29/74	Alley et al.			
		3,995,617	12/07/76	Watkins et al.			
		4,014,317	03/29/77	Bruno			
		4,038,519	07/26/77	Foucras			
		4,111,209	09/05/78	Wolvek et al.			
		4,246,932	01/27/81	Raines			
		4,298,006	11/03/81	Parks			
		4,393,863	07/19/83	Osterholm			
		4,445,514	05/01/84	Osterholm			
		4,445,887	05/01/84	Osterholm			
		4,445,888	05/01/84	Osterholm			
		4,446,154	05/01/84	Osterholm			
		4,446,155	05/01/84	Osterholm			
		4,450,841	05/29/84	Osterholm			
		4,451,251	05/29/84	Osterholm			
		4,470,407	09/11/84	Hussein			
		4,540,402	09/10/85	Aigner			

### FOREIGN PATENT DOCUMENTS

Exr's. Init.	Cite #	Document No.	Date	Country	Class	Sub	Translation? Yes No
		WO 91/05528	05/02/91	Granulab B.V.			

Examiner	Date Considered
----------	-----------------

\* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., ~~citation~~) if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449 (Modified)</b>				Docket No.: RADME-65146		Serial No.:	
<b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b> Page 2 of 8				Applicant: Machold et al.			
				Filing Date:		Prior Art Unit: 3736	
<b>UNITED STATES PATENT DOCUMENTS</b>							
*Exr's. Inits.	Cite #	Patent No.	Date	Name	Class	Sub Class	Filing Date (if applicable)
		4,657,532	04/14/87	Osterholm			
		4,661,094	04/28/87	Simpson			
		4/662,383	05/05/87	Sogawa et al.			
		4,672,962	06/16/87	Hershenson			
		4,686,085	08/11/87	Osterholm			
		4,701,166	10/20/87	Groshong et al.			
		4,705,501	11/10/87	Wigness et al.			
		4,748,979	06/07/88	Hershenson			
		4,754,752	07/05/88	Ginsburg et al.			
		4,758,431	07/19/88	Osterholm			
		4,769,005	09/06/88	Ginsburg et al.			
		4,795,423	01/03/89	Osterholm			
		4,804,358	02/14/89	Karcher et al.			
		4,819,655	04/11/89	Webler			
		4,830,849	05/16/89	Osterholm			
		4,857,054	08/15/89	Helfer			
		4,873,978	10/17/89	Ginsburg			
		4,892,095	01/09/90	Nakhgevany			
		4,892,519	01/09/90	Songer et al.			
		4,899,741	02/13/90	Bentley et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
Exr's. Init.	Cite #	Document No.	Date	Country	Class	Sub	Translation? Yes No
Examiner				Date Considered			
* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., <del>citation</del> ) if not in conformance and not considered. Include copy of this form with next communication to applicant.							

<b>FORM PTO-1449 (Modified)</b>				Docket No.: RADME-65146		Serial No.:		
<b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b> Page 3 of 8				Applicant: Machold et al.				
				Filing Date:		Prior Art Unit: 3736		
<b>UNITED STATES PATENT DOCUMENTS</b>								
*Exr's. Inits.	Cite #	Patent No.	Date	Name	Class	Sub Class	Filing Date (if applicable)	
		4,909,252	03/20/90	Goldberger				
		4,920,963	05/01/90	Brader				
		4,941,475	07/17/90	Williams et al.				
		4,963,130	10/16/90	Osterholm				
		4,976,691	12/11/90	Sahota				
		4,981,691	01/01/91	Osterholm et al.				
		4,995,863	02/26/91	Nichols et al.				
		5,011,488	04/30/91	Ginsburg				
		5,019,075	05/28/91	Spears et al.				
		5,030,210	07/09/91	Alchas				
		5,041,089	08/20/91	Mueller et al.				
		5,085,630	02/04/92	Osterholm et al.				
		5,092,841	03/03/92	Spears				
		5,106,360	04/21/92	Ishiwara et al.				
		5,112,301	05/12/92	Fenton, Jr. et al.				
		5,147,385	09/15/92	Beck et al.				
		5,149,321	09/22/92	Klatz et al.				
		5,151,100	09/29/92	Abele et al.				
		5,174,285	12/29/92	Fontenot				
		5,180,364	01/19/93	Ginsburg				
<b>FOREIGN PATENT DOCUMENTS</b>								
Exr's. Init.	Cite #	Document No.	Date	Country	Class	Sub	Translation? Yes No	
Examiner					Date Considered			
* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., <del>citation</del> ) if not in conformance and not considered. Include copy of this form with next communication to applicant.								

<b>FORM PTO-1449</b> (Modified)				Docket No.: RADME-65146		Serial No.:	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT Page 4 of 8				Applicant: Machold et al.			
				Filing Date:		Prior Art Unit: 3736	
<b>UNITED STATES PATENT DOCUMENTS</b>							
*Exr's. Inits.	Cite #	Patent No.	Date	Name	Class	Sub Class	Filing Date (if applicable)
		5,191,883	03/09/93	Lennox et al.			
		5,196,024	03/23/93	Barath			
		5,211,631	05/18/93	Sheaff			
		5,216,032	06/01/93	Manning			
		5,234,405	08/10/93	Klatz et al.			
		5,248,312	09/28/93	Langberg			
		5,250,070	10/05/93	Parodi			
		5,257,977	11/02/93	Eshel			
		5,261,399	11/16/93	Klatz et al.			
		5,269,758	12/14/93	Taheri			
		5,342,301	08/30/94	Saab			
		5,344,436	09/06/94	Fontenot et al.			
		5,368,591	11/29/94	Lennox et al.			
		5,395,314	03/07/95	Klatz et al.			
		5,403,281	04/04/95	O'Neill et al.			
		5,437,633	08/01/95	Manning			
		5,437,673	08/01/95	Baust et al.			
		5,486,208	01/23/96	Ginsburg			
		5,531,776	07/02/96	Ward et al.			
		5,584,804	12/17/96	Klatz et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
Exr's. Init.	Cite #	Document No.	Date	Country	Class	Sub	Translation? Yes No
Examiner				Date Considered			
* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., <del>citation</del> ) if not in conformance and not considered. Include copy of this form with next communication to applicant.							

<b>FORM PTO-1449 (Modified)</b>				Docket No.: RADME-65146		Serial No.:	
<b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b> Page 5 of 8				Applicant: Machold et al.			
				Filing Date:		Prior Art Unit: 3736	
<b>UNITED STATES PATENT DOCUMENTS</b>							
*Exr's. Inits.	Cite #	Patent No.	Date	Name	Class	Sub Class	Filing Date (if applicable)
		5,624,392	04/29/97	Saab			
		5,653,692	08/05/97	Masterson et al.			
		5,676,691	10/14/97	Friedman			
		5,678,570	10/21/97	Manning			
		5,716,386	02/10/98	Ward et al.			
		5,733,319	03/31/98	Neilson et al.			
		6,019,783	02/01/00	Philips et al.			
		6,042,559	03/28/00	Dobak, III			
		6,126,684	10/03/00	Gobin et al.			
		6,146,411	11/14/00	Noda et al.			
		6,149,670	11/21/00	Worthen et al.			
		6,149,677	11/21/00	Dobak, III			
		6,245,095 B1	06/12/01	Dobak, III et al.			
		6,287,326 B1	09/11/01	Pecor			
		6,290,717 B1	09/18/01	Philips			
		6,299,599 B1	10/09/01	Pham et al.			
		6,312,452 B1	11/06/01	Dobak, III et al.			
		6,338,727 B1	01/15/02	Noda et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
Exr's. Init.	Cite #	Document No.	Date	Country	Class	Sub	Translation? Yes No
Examiner				Date Considered			
* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶ 609. Draw line through citation (i.e., <del>citation</del> ) if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	
				Filing Date	
				First Named Inventor	Machold et al.
				Group Art Unit	Prior: 3736
				Examiner Name	Unassigned
				Attorney Docket Number	RADME- 65146
Sheet	6	of	8		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
		LONG, R., "Regional Cranial Hypothermia in the Prevention of Cerebral Ischemic Damage During Carotid Occlusion," <i>Review of Surgery</i> , May-June 1966, pp. 226-228, Vol. 23, No. 3	
		WHITE, R. et al., "Profound selective cooling and ischemic of primate brain without pump or oxygenator," <i>Surgery</i> , July, 1969, pp. 224-232, Vol. 66, No. 1	
		WEALE, F.E., "The Aneroid Manometer in Peripheral Arterial Surgery," <i>The British Journal of Surgery</i> , August, 1969, pp. 612-613, 630-631, Vol. 56, No. 8	
		NEGRIN, JR., J., "The Hypothermostat, An Instrument to Obtain Local Hypothermia of the Brain or Spinal Cord," <i>International Surgery</i> , August 1970, pp. 2, 93-106, Section 1, Vol. 54, No. 2	
		SAFAR, P. et al., "Resuscitation after global brain ischemic-anoxia," <i>Critical Care Medicine</i> , July-August 1978, pp. 215-227, Vol. 6, No. 4	
		PING, F.C. et al., "Protection of the Brain From Hypoxia: A Review," <i>Canadian Anaesthetists' Society Journal</i> , November 1978, pp. 468-473, Vol. 25, No. 6	
		SAFAR, P., "Dynamics of Brain Resuscitation After Ischemic Anoxia," <i>Hospital Practice</i> , February 1981, pp. 67-72	
		GISVOLD, S. et al., "Multifaceted Therapy After Global Brain Ischemia in Monkeys," <i>Stroke</i> , September-October 1984, pp. 803-812, Vol. 15, No. 5	
		LEONOV, Y. et al., "Mild Cerebral Hypothermia during and after Cardiac Arrest Improves Neurologic Outcome in Dogs," <i>Journal of Cerebral Blood Flow and Metabolism</i> , (1990), pp. 57-70, Vol. 10, No. 1	
		MINAMISAWA, H. et al., "The Effect of Mild Hyperthermia and Hypothermia on Brain Damage Following, 5, 10, and 15 Minutes of Forebrain Ischemia," <i>American Neurological Association</i> , July 1990, pp. 26-33, Vol. 28, No. 1	
		TISHERMAN, S. et al., "Therapeutic Deep Hypothermic Circulatory Arrest in Dogs: A Resuscitation Modality for Hemorrhagic Shock with 'Irreparable' Injury," <i>The Journal of Trauma</i> , July 1990, pp. 836-847, Vol. 30, No. 7	
		TISHERMAN, S. et al., "Deep Hypothermic Circulatory Arrest Induced During Hemorrhagic Shock in Dogs: Preliminary Systemic and Cerebral Metabolism Studies," <i>Current Surgery</i> , September-October 1990, pp. 327-330	
		LEONOV, Y. et al., "Moderate Hypothermia After Cardiac Arrest of 17 Minutes in Dogs: Effect on Cerebral and Cardiac Outcome," <i>Stroke</i> , November 1990, pp. 1600-1606, Vol. 21, No. 11	
		STERZ, F. et al., "Mild Hypothermic Cardiopulmonary Resuscitation Improves Outcome after Prolonged Cardiac Arrest in Dogs," <i>Critical Care Medicine</i> , March 1991, pp. 379-389, Vol. 19, No. 3	
		TISHERMAN, S. et al., "Profound Hypothermia (<10°C) Compared with Deep Hypothermia (15°C) Improves Neurologic Outcome in Dogs After Two Hours' Circulatory Arrest Induced to Enable Resuscitative Surgery," <i>The Journal of Trauma</i> , August 1991, pp. 1051-1062, Vol. 31, No. 8	
		DIETRICH, W., "The Importance of Brain Temperature in Cerebral Injury," <i>Journal of Neurotrauma</i> , (1992), pp. S475-S485, Supplement 2	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--



Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	
				Filing Date	
				First Named Inventor	Machold et al.
				Group Art Unit	Prior: 3736
				Examiner Name	Unassigned
Sheet	7	of	8	Attorney Docket Number	RADME 65146

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
		GINSBERG, M. et al., "Therapeutic Modulation of Brain Temperature: Relevance to Ischemic Brain Injury," <i>Cerebrovascular and Brain Metabolism Reviews</i> , (1992), pp. 189-225, Vol. 4, No. 3	
		MARTINEZ-ARIZALA, A. et al., "Hypothermia in Spinal Cord Injury," <i>Journal of Neurotrauma</i> , May 1992, pp. S497-S505, Vol. 9, Suppl. 2	
		WEINRAUCH, V. et al., "Beneficial Effect of Mild Hypothermia and Detrimental Effect of Deep Hypothermia After Cardiac Arrest in Dogs," <i>Stroke</i> , October 1992, pp. 1454-1462, Vol. 23, No. 10	
		KUBOYAMA, K. et al., "Delay in cooling negates the beneficial effect of mild resuscitative cerebral hypothermia after cardiac arrest in dogs: A prospective, randomized study," <i>Critical Care Medicine</i> , September 1993, pp. 1348-1358, Vol. 21, No. 9	
		MAHER, J. et al., "Hypothermia as a Potential Treatment for Cerebral Ischemia," <i>Cerebrovascular and Brain Metabolism Reviews</i> , September 1993, pp. 277-300, Vol. 5, No. 4	
		SAFAR, P., "Cerebral Resuscitation After Cardiac Arrest: Research Initiatives and Future Directions," <i>Annals of Emergency Medicine</i> , February 1993, pp. 324-389, Vol. 22, No. 2, Part 2	
		OKU, K. et al., "Mild Hypothermia After Cardiac Arrest in Dogs Does Not Affect Postarrest Multifocal Cerebral Hypoperfusion," <i>Stroke</i> , October 1993, pp. 1590-1597, Vol. 24, No. 10	
		KUBOYAMA, K. et al., "Mild hypothermia after cardiac arrest in dogs does not affect postarrest cerebral oxygen uptake/delivery mismatching," <i>Resuscitation</i> 27, (1994), pp. 231-244	
		LAPTOOK, A. et al., "Modest Hypothermia Provides Partial Neuroprotection for Ischemic Neonatal Brain," <i>Pediatric Research</i> , (1994), pp. 436-442, Vol. 35, No. 4	
		ONOE, M. et al., "The effect of pulsatile perfusion on cerebral blood flow during profound hypothermia with total circulatory arrest," <i>Journal of Thoracic and Cardiovascular Surgery</i> , July 1994, pp. 119-125, Vol. 108	
		XIAO, F. et al., "Peritoneal cooling for mild cerebral hypothermia after cardiac arrest in dogs," <i>Resuscitation</i> 30, (1995), pp. 51-59	
		SESSLER, D., "Deliberate Mild Hypothermia," <i>Journal of Neurosurgical Anesthesiology</i> , January 1995, pp. 38-46, Vol. 7, No. 1	
		CAPONE, A. et al., "Complete Recovery after Normothermic Hemorrhagic Shock and Profound Hypothermic Circulatory Arrest of 60 Minutes in Dogs," <i>The Journal of Trauma: Injury, Infection, and Critical Care</i> , March 1996, pp. 388-395, Vol. 40, No. 3	
		GISVOLD, S. et al., "Cerebral resuscitation from cardiac arrest: Treatment potentials," <i>Critical Care Medicine</i> , (1996), pp. S69-S80, Vol. 24, No. 2 (Suppl.)	
		KATAOKA, K. et al., "Ischemic Neuronal Damage: How Does Mild Hypothermia Modulate It?", <i>Molecular and Chemical Neuropathology</i> , (1996), pp. 191-195, Vol. 28	
		SAFAR, F. et al., "Selective brain cooling after cardiac arrest," <i>Critical Care Medicine</i> , (1996), pp. 911-914, Vol. 24, No. 6	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	
				Filing Date	
				First Named Inventor	Machold et al.
				Group Art Unit	Prior: 3736
				Examiner Name	Unassigned
				Attorney Docket Number	RADME- 65146
Sheet	8	of	8		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
		STERZ, F. et al., "Mild Resuscitative Hypothermia and Outcome After Cardiopulmonary Resuscitation," <i>Journal of Neurosurgical Anesthesiology</i> , January 1996, pp. 88-96, Vol. 8, No. 1	
		WASS, C. et al., "Hypothermia-associated Protection from Ischemic Brain Injury: Implications for Patient Management, <i>International Anesthesiology Clinics: Topics of Neuroanesthesia</i> , Fall 1996, pp. 95-111, Vol. 34, No. 4	
		SAFAR, P. et al., "Improved Cerebral Resuscitation From Cardiac Arrest in Dogs With Mild Hypothermia Plus Blood Flow Promotion," <i>Stroke</i> , January 1996, pp. 105-113, Vol. 27, No. 1	
		MARION, D. et al., "Resuscitative hypothermia," <i>Critical Care Medicine</i> , February 1996, pp. S81-S89, Vol. 24, No. 2 (Suppl.)	
		ROSOMOFF, H. et al., "Resuscitation from severe brain trauma," <i>Critical Care Medicine</i> , February 1996, pp. S48-S56, Vol. 24, No. 2 (Suppl.)	
		MARKARIAN, G. et al., "Mild Hypothermia: Therapeutic Window After Experimental Cerebral Ischemia," <i>Neurosurgery</i> , March 1996, pp. 542-551, Vol. 38, No. 3	
		HOFFMAN, W. et al., "Effects of graded hypothermia on outcome from brain ischemic," <i>Neurological Research</i> , April 1976, pp. 185-189, Vol. 18, No. 2	
		SCHWARTZ, A. et al., "Isolated Cerebral Hypothermia by Single Carotid Artery Perfusion of Extracorporeally Cooled Blood in Baboons," <i>Neurosurgery</i> , September 1996, pp. 577-582, Vol. 39, No. 3	
		METZ, C. et al., "Moderate hypothermia in patients with severe head injury: cerebral and extracerebral effects," <i>Journal of Neurosurgery</i> , October 1996, pp. 533-541, Vol. 85, No. 4	
		BARONE, F. et al., "Brain Cooling During Transient Focal Ischemia Provides Complete Neuroprotection," <i>Neuroscience and Biobehavioral Reviews</i> , " (1997), pp. 31-44, Vol. 21, No. 1	
		TISHERMAN, S. et al., "Future directions for resuscitation research. V. Ultra-advanced life support," <i>Resuscitation</i> 34, (1997), pp. 281-293	
		COLBOURNE, F. et al., "Postischemic Hypothermia: A Critical Appraisal with Implications for Clinical Treatment," <i>Molecular Neurobiology</i> , June 1997, pp. 171-201, Vol. 14, No. 3	
		NESBIT, G. et al., "Intracranial Intraarterial thrombolysis facilitated by microcatheter navigation through an occluded cervical internal carotid artery," <i>Journal Neurosurgery</i> , March 1996, pp. 387-392, Vol. 84	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--